

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

|                                   |   |                     |
|-----------------------------------|---|---------------------|
| ROQUETTE FRERES,                  | ) |                     |
|                                   | ) |                     |
| Plaintiff,                        | ) |                     |
|                                   | ) |                     |
| v.                                | ) | C.A. No. 06-540-GMS |
|                                   | ) |                     |
| SPI PHARMA, INC., <i>et al.</i> , | ) |                     |
|                                   | ) |                     |
| Defendants.                       | ) |                     |

**DEFENDANT SPI PHARMA, INC.'S RESPONSE TO PLAINTIFF  
ROQUETTE FRERES' MOTION FOR LEAVE TO FILE A SUR-REPLY BRIEF**

Defendant SPI Pharma, Inc. ("SPI") hereby responds to plaintiff Roquette Freres' ("Roquette") Motion for Leave to File a Sur-Reply Brief in Opposition to SPI Pharma, Inc.'s Reply Brief, and respectfully requests that the Court deny Roquette's motion, for the reasons stated herein.<sup>1</sup>

1. On December 28, 2007, SPI moved to amend its answer to add an affirmative defense and counterclaim of unenforceability due to inequitable conduct ("Motion to Amend") (D.I. 147). The proposed First Amended Answer, attached to the Motion to Amend, contains detailed factual allegations in support of the inequitable conduct defense and counterclaim. (D.I. 147, Ex. A). SPI showed in its supporting opening brief ("Op. Br.") that Roquette "(i) misrepresented the content of the prior art in the '777 patent specification; and (ii) mischaracterized and withheld material information concerning the comparative data presented in Examples 2 and 3, and associated tables, in the '777 patent." (D.I. 148 at 1).

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<sup>1</sup> Pursuant to LR 7.1.2(a), SPI hereby waives its right to file a separate answering brief in opposition to Roquette's motion.

2. After SPI filed its reply brief, Roquette filed a motion for leave to file a sur-reply brief ("Sur-Reply Motion") (D.I. 156). Roquette simultaneously filed, as attachments to the Sur-Reply Motion, its proposed sur-reply brief and exhibit to the brief. (D.I. 157 & 158) This is not the first time Roquette has attached additional briefing to a motion for leave to file such briefing in violation of Local Rule 7.1.2, nor is it the first time SPI has argued that this practice does not comport with the Local Rules. (*See* D.I. 129, 132, & 133).

3. SPI gave as complete an argument as possible as to why its pleading was timely, not prejudicial, and not futile in its opening brief (Op. Br. at 7-10) without the benefit of Roquette's theories. In its answering brief, Roquette focused heavily on specific factual allegations raised by SPI, which led SPI to reply with more detailed explanations for its allegations. Roquette's claim of unfair surprise is wrong. Each and every statement in SPI's reply brief is well within the theories set out in the proposed Amended Answer and opening brief in support of the Motion to Amend, as set forth in paragraphs 5 through 7 below.

4. Roquette's Sur-Reply Motion, like its answering brief, focuses on the meaning and interpretation of the facts alleged by SPI in its proposed First Amended Answer. However, the resolution of the issue of inequitable conduct on the merits is neither necessary nor proper at the motion to amend stage, as the Court must accept all of the facts in the proposed pleading as true, and make all reasonable inferences in SPI's favor. The Court should not weigh the evidence or reach the merits of every factual argument and counter-argument as Roquette urges. Instead, the Court need only decide whether the proposed First Amended Answer satisfies the liberal amendment standard of Fed. R. Civ. P. 15(a), and SPI argues that it most certainly does.

Roquette's Sur-Reply is Improper and Unnecessary Because SPI's Reply Brief Did Not Raise Any New Arguments

5. SPI's reply brief does not contain "new allegations" that "shift its arguments to significantly different theories," as Roquette argues. Sur-Reply Motion at 1. On the contrary, the arguments made by SPI in its reply brief were raised in SPI's opening brief or in response to arguments in Roquette's answering brief. SPI's allegations were of course also present in the proposed First Amended Answer, and, because all facts in the amended pleading must be accepted as true when considering a motion to amend (as in considering a motion to dismiss under Fed. R. Civ. P. 12(b)(6)), additional factual arguments by Roquette in its sur-reply are improper and unnecessary. Op. Br. at 9; *Banks v. Wolk*, 918 F.2d 418, 419 (3d Cir. 1990) (holding that in reviewing the propriety of a refusal to allow amendment, "we must accept as true all factual allegations in the amended complaint and all reasonable inferences that can be drawn from them.").

6. In particular, Roquette argues in its Sur-Reply Motion<sup>2</sup> that SPI advances for the first time allegations related to: the inadequacy of the description of certain pieces of prior art (JP 61-85331 and JP 61-85330) in the specification of the '777 patent; Roquette's misleading presentation of data in the table associated with Example 2 in the '777 patent; and Roquette's withholding of data from the table associated with Example 3 in the '777 patent. Sur-Reply Motion at 2. In fact, SPI extensively discussed Roquette's statements regarding the two pieces of prior art (JP 61-85331 and JP 61-85330) in the '777 patent specification in its opening and reply briefs on the Motion to Amend, and in the proposed First Amended Answer. See Op. Br. at 2-3; First Amended Answer at ¶¶ 31-36. The same is true for SPI's allegations regarding the

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<sup>2</sup> Because Roquette improperly filed its sur-reply as an attachment to its motion, rather than waiting for the Court to grant leave, SPI will not here present substantive responses to the allegations in the sur-reply brief, which, in any event, would be more properly presented at summary judgment or trial.

data presented in (or withheld from) the tables associated with Examples 2 and 3 in the specification of the '777 patent. *See* Op. Br. at 4-6; First Amended Answer at ¶¶ 43-50.

7. All of the allegations in SPI's reply brief with respect to the prior art disclosures and tables in the specification of the '777 patent are well within the scope of the theories set out in the proposed First Amended Answer and opening brief in support of the Motion to Amend, and, in addition, are offered in direct response to Roquette's argument that amendment of SPI's Answer, Defenses, and Counterclaims would be futile. *See* Ans. Br. at 10. A sur-reply is improper and unnecessary under such circumstances. *See In re: Valley Media, Inc.*, Civ. No. 05-179-JJF, 2006 U.S. Dist. LEXIS 7669, at \*10 n.2 (D. Del. Feb. 28, 2006) (denying motion for leave to file a sur-reply brief where "[e]ach of the issues addressed in the sur-reply were properly raised by Appellant in its Opening Brief, and the Court does not find the Sur-Reply to be necessary to respond to any new arguments raised for the first time in Appellant's Reply Brief."); *Millett v. Truelink, Inc.*, Civ. No. 05-599-SLR, 2006 U.S. Dist. LEXIS 63875, at \*1 n.1 (D. Del. Sept. 7, 2006) (denying plaintiffs' motion to file a sur-reply where plaintiffs previously had "ample opportunity" to brief the issues they sought to address in the sur-reply); *Vandenbraak v. Alfieri*, Civ. No. 01-482 (KAJ), 2005 U.S. Dist. LEXIS 9882, at \*2 n.2 (D. Del. May 25, 2005) (denying motion for leave to file sur-reply where "[n]o argument beyond the standard briefing is necessary or appropriate").

Roquette Seeks to Argue the Merits of Factual Allegations, Which is Improper on a Rule 15 Motion to Amend

8. Roquette seems concerned that it will not be able to present every one of its counter-arguments to SPI's substantive inequitable conduct arguments. But SPI was not, by its Motion to Amend, asking this Court to decide issues of inequitable conduct. Roquette cannot lose, nor can SPI win, the issue of unenforceability due to inequitable conduct on these papers. "[W]hether there has been a misrepresentation with the requisite intent [is a] question[] of fact to be determined by the court during the presentation of the evidence on inequitable conduct" and not a question to be resolved at the amendment stage. *Amgen, Inc. v. Ariad Pharms., Inc.*, Civ. No. 06-259-MPT, 2008 U.S. Dist. LEXIS 7317, at \*6 (D. Del. Jan. 31, 2008). Rather, the question for the Court is whether the proposed amendment states a claim for inequitable conduct taking all pleaded facts and reasonable inferences therefrom as true. *See Banks*, 918 F.2d at 419; *Enzo Life Scis., Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 490 (D. Del. 2003) (allowing amendment to add a defense and counterclaim of inequitable conduct where "the Court cannot conclude with certainty, at this juncture, that [defendant] can prove no set of facts in support of [its] claim which would entitle [it] to relief") (quotations and citation omitted). If the amendment is allowed, both parties will later have an opportunity to submit to the Court their complete arguments as to whether or not Roquette's actions constituted inequitable conduct before the United States Patent & Trademark Office.

9. As Roquette concedes, there is a liberal standard for amendment of pleadings under Federal Rule of Civil Procedure 15(a). *Ans. Br.* at 9; *Alvin v. Suzuki*, 227 F.3d 107, 111 (3d Cir. 2000) (noting the "liberal amendment provisions of Rule 15"). SPI has sufficiently alleged the elements of inequitable conduct to justify amendment under Rule 15(a) and consistently argued the same theories of inequitable conduct throughout its briefing in support of

its Motion to Amend. Thus, a sur-reply by Roquette further arguing the merits of its inequitable conduct position is improper and unnecessary, and Roquette's Sur-Reply Motion should be denied.

Roquette's Filing of Its Sur-Reply Brief was Procedurally Improper

10. In addition to being substantively improper and unnecessary, Roquette's sur-reply is procedurally improper for two reasons. First, it is not restricted to the citation of subsequently-decided authorities and therefore was improperly filed without court approval. *See* LR 7.1.2(b) (explaining that after standard briefing on an issue is complete, "[e]xcept for the citation of subsequent authorities, no additional papers shall be filed absent Court approval."); *Chesapeake Utils. Corp. v. Am. Home Assurance Co.*, 704 F. Supp. 551 (D. Del. 1989) (denying motion for leave to supplement brief where the motion was filed after the briefing period and was not made for the purposes of adding later-decided cases or addressing issues that arose on oral argument). Second, the attachment of the sur-reply brief to the Sur-Reply Motion was improper. *See* LR 7.1.2; *Kondrath v. Arum*, 881 F. Supp. 925, 927 (D. Del. 1995); *Novartis Pharms. Corp. v. Abbott Labs.*, C.A. No. 00-784-JJF, slip op. at 2 (D. Del. Feb. 20, 2002) (attached as Ex. A) (refusing to consider sur-reply briefs attached to motions for leave as filed in violation of Local Rule 7.1.2).

WHEREFORE, Defendant SPI Pharma, Inc. respectfully requests that this Court deny Plaintiff Roquette Freres' Motion for Leave to File a Sur-Reply Brief in Opposition to SPI Pharma, Inc.'s Reply Brief.

Respectfully submitted,

YOUNG CONAWAY STARGATT  
& TAYLOR, LLP



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Dated: February 21, 2008

**CERTIFICATE OF SERVICE**

I, Jeffrey T. Castellano, hereby certify that on February 21, 2008, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on February 21, 2008, I caused a copy of the foregoing document to be served by e-mail and hand delivery on the above-listed counsel of record and on the following in the manner indicated:

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# **EXHIBIT A**

FILED  
CLERK U.S. DISTRICT COURT  
DISTRICT OF DELAWARE

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE  
FEB 20 PM 3:35

NOVARTIS PHARMACEUTICALS  
CORPORATION

Plaintiff,

v.

ABBOTT LABORATORIES,

Defendant.

Civil Action No. 00-784-JJF

O R D E R


WHEREAS presently pending before the Court is a Motion To Strike Novartis' Responsive Claim Construction Brief, Or In The Alternative, Motion For Leave To File A Surreply Claim Construction Brief (D.I. 138) filed by Defendant Abbott Laboratories (hereinafter "Abbott") and a Motion For Leave To File A Reply Brief In Response To Defendant Abbott's Responsive And Surreply Claim Construction Briefs (D.I. 143) filed by Plaintiff Novartis Pharmaceuticals Corporation's (hereinafter "Novartis");

WHEREAS, the Court concludes that additional disputed terms are now in dispute;

WHEREAS, the parties have filed their proposed "Surreply" and "Reply" briefs as exhibits to their respective Motions (D.I. 138, Ex. A; D.I. 144, Ex. A) in violation of Local Rule 7.1.2 (c);

NOW THEREFORE, IT IS HEREBY ORDERED this 20 day of  
February, 2002 that:

- 1) Abbott's Motion To Strike Novartis' Responsive Claim  
Construction Brief (D.I. 138-1) is DENIED;
- 2) Abbott's Motion For Leave To File A Surreply Claim  
Construction Brief (D.I. 138-2) is GRANTED;
- 3) Novartis' Motion For Leave To File A Reply Brief In  
Response To Defendant Abbott's Responsive And Surreply  
Claim Construction Briefs (D.I. 143) is GRANTED;
- 4) Abbott and Novartis shall formally file their  
respective "Surreply" and "Reply" briefs with the Court  
within ten (10) days of the date of this Order;
- 5) No further claim construction briefing will be  
permitted.

  
UNITED STATES DISTRICT JUDGE